

### **REMARKS**

Claims 9-16 are pending in the present application. The Office Action and cited references have been considered. Favorable reconsideration is respectfully requested.

The Abstract was objected to because it allegedly included legal terminology. Amendments have been made to the Abstract to address this concern. Withdrawal of this objection is respectfully requested.

Claims 12 was rejected under 35 U.S.C. §112, second paragraph. The patent number has been withdrawn from the claim. Withdrawal of this rejection is respectfully requested.

Claims 9-12 were rejected under 35 U.S.C. §103 as being unpatentable over Jorneus (U.S. Patent No. 5,741,267) in view of Meller (U.S. Patent Application No. 2004/0210229). This rejection is respectfully traversed for the following reasons.

The Examiner asserts that Jorneus discloses a milling procedure that comprises the same phases as the milling procedure claimed in claim 9 of the present application, except that Jorneus does not disclose

the tissue particles displaced or extracted as a result of the milling process are collected for subsequent use in other surgical processes, the recovery of the tissue is not being dependent on the use of suction machines and being based on that the tissue displaced or extracted during the milling process is housed in the milling tool as a result of the retentive design of the tool, so that when the tool is taken out these particles are extracted from it and can be used or stored as appropriate for other surgical uses, and the tissue particles collected during the milling process are mixed with Plasma Rich in Growth Factors or with other biological materials for desirable medical purposes.

The Examiner asserts that Meller discloses the collection of displaced or extracted tissue particles as a result of the milling process, which are collected for subsequent use in other surgical processes. He also asserts that Meller discloses the fact that the displaced tissue particles are housed in the milling tool as a result of the retentive design of the tool. Finally, he concludes that it would have been obvious to

have constructed the method of Jorneus et al. to including collection of collecting the tissue particles displaced or extracted as a result of the milling process for subsequent use in other surgical processes, the recovery not being dependent on the use of suction machines and so that when the tool is taken out these particles are extracted from it and can be used or stored as appropriate for other surgical uses as taught by Meller to better fixate the implant within the milled out surgical site.

However, Applicant respectfully submits that the retention shown in Meller does not match that of the present application. In Meller, the drill bit (20) drills inside a container (12); tissue particles that come off the bone because of drilling are collected by and inside the container (12). However, in the present application, the tissue particles are collected in the drill bit itself (8), specifically in retention areas (17) between adjacent spiral grooves (11).

Claim 9 of the present application has been amended to clarify this technical distinction, as follows:

9. Milling procedure to be carried out on the bone, cartilage or other patient tissue in order to form a cavity of a shape and size that allows it to house an implant or prosthesis or for other purposes in which a cavity needs to be formed, with said procedure being based on the repeated application of various rotating **mill bits** on the tissue until the required cavity is formed, with said procedure comprising an intermediate phase in which the depth, width and other main features of the cavity are defined and an optional countersinking phase in which the mouth of the cavity is widened, wherein:

- the **mill bits** used during the intermediate and countersinking phases are operated at low speeds ranging between 20 and 80 rpm;
- during the intermediate phase, the countersinking phase, or both, the tissue particles displaced or extracted as a result of the milling process are collected for subsequent use in other surgical processes, the recovery of the tissue is not being dependent on the use of suction machines and being based on that the tissue displaced or extracted during the milling process is housed in the **mill bit** as a result of the retentive design of the **mill bit, the mill bit comprising tissue particle retention areas between adjacent spiral grooves**, so that when the **mill bit** is taken out these particles are extracted from **said retention areas** and can be used or stored as appropriate for other surgical uses.

The Examiner also asserts that having the mill bits rotate at low speeds (20 80 rpm) is not patentable, as the milling procedure is known and this is just an optimum or workable range. Applicant does not agree: the present application is not claiming an optimum range; actually, bone milling procedures are usually performed at high drilling speed because this optimizes the time of treatment: drilling is faster, among other advantages. But, Applicant is claiming a different procedure (not an optimum milling procedure, in general) which would be used when the surgeon wants to recover bone particles to use them for another application (for example, grafting). In this case, if bone particles are to be collected and used, Applicant has discovered that low-speed milling is suitable because it does not harm bone particles (no over-heating is produced) and it allows extraction of the particles by them being retained in the mill bit (low-speed also contributes to correct retention of bone particles in the mill bit).

Paragraph [0005] of US20070293867 (the present published application), states "The wide variety of implants and mill bits used in conventional techniques means, therefore, that a broad range of milling speeds - from 800 to 1,500 rpm approximately - is used. This high-speed milling, as it is referred to, causes both the mill

bit and the bone tissue it operates on to heat up with the temperature of the mill bit exceeding 40°C.... Thus, with the convention milling speeds, significant disadvantages result which precludes their use in the present application.

Paragraph [0036] explains the advantageous effect of the invention, in other words, the effect of solving the problem of excessive heating:

Tests have shown that the milling technique according to the invention does not cause the temperature of the mill bits to increase by more than five degrees centigrade, which, when added to the ambient temperature, means that the temperature is kept below 40 degrees centigrade—the point at which insult and even necrosis occurs.

In paragraph [0037], Applicant explains how tests have shown that extracted bone cells are ideally suited (not just plain suited) for their use in autografting:

Tests using optical and electronic microscopes have also shown that the bone particles extracted during the milling process retain their osteogenic (deriving from bone-forming tissue), osteoinductive (inducing other cells to form bone) and osteoconductive (providing structural support during bone regeneration) properties. The bone particles are, therefore, ideally suited for use in autografting. Autografting, for example, can be performed by mixing the bone particles with PRGF (Plasma Rich in Growth Factors, according to invention WO0044314 awarded to this applicant). Another potential autografting method involves keeping the particles in physiological serum or in the patient's blood. The mixture can later be used in autografting.

Thus, the present claimed milling speeds provide unexpected results and advantages not found in the prior art.

For at least these reasons, Applicant respectfully submits that claim 9 is patentable over the cited prior art, whether taken alone or in combination as proposed in the Office Action. Claims 2-12 are believed to be patentable in and of themselves and for the reasons discussed above with respect to claim 9.

In view of the above amendment and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections of record. Applicant submits that the application is in condition for allowance and early notice to this effect is most earnestly solicited.

If the Examiner has any questions, he is invited to contact the undersigned at 202-628-5197.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By /Ronni S. Jillions/  
Ronni S. Jillions  
Registration No. 31,979

RSJ:me  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
G:\BN\O\Ocha\Anitua6\pto\2010-12-09Response.doc